



AF/1631 *EIFW*

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 09/807,943
Applicant : Yan HONG et al.
Filed : April 20, 2001
TC/A.U. : 1631
Examiner : Channing S. Mahatan

Docket No. : 2977-123
Customer No. : 06449
Confirmation No. :

TRANSMITTAL OF APPEAL BRIEF

Mail Stop - Appeal Brief-Patents
Director of the United States Patent
and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Enclosed in connection with the above-referenced application is an Appeal Brief with Appendix in triplicate. A check is enclosed to cover the following fees: \$330.00 to cover the fee for filing a brief in support of a notice of appeal.

Also, please charge any additional fees or credit any overpayment to Deposit Account No. 02-2135. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

ROTHWELL, FIGG, ERNST & MANBECK, p.c.

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2977-123

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of) **BEFORE THE BOARD OF PATENT**
Yan HONG et al.) **APPEALS AND INTERFERENCES**
Serial No. 09/807,943) Appeal No.:
Filed: April 20, 2001) Examiner: Channing Mahatan
For: DNA MARKER PROFILE DATA) Group Art Unit: 1631
ANALYSIS) July 28, 2004

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an appeal from the final rejection of claims 1-7, 9-14, 16 and 17 of the above-identified application, which claims were finally rejected in the Office action dated January 29, 2004. A Notice of Appeal was timely filed on May 28, 2004.

REAL PARTY IN INTEREST

The real party in interest in this case is Exploit Technologies Pte Ltd. of Singapore.

07/28/2004 JBALINAN 00000015-09807943

01 FC:1401

330.00 DP

07/29/2004 JBALINAN 00000090 09807943

01 FC:1402

330.00 DP

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

STATUS OF THE CLAIMS

Claims 1-17 are pending in the application. Claims 1-7, 9-14, 16 and 17 stand finally rejected, and claims 8 and 15 stand objected to as being dependent upon a rejected base claim, but otherwise have been indicated to be allowable. Claims 1, 12 and 17 constitute the independent claims on appeal. This appeal is directed to claims 1-7, 9-14, 16 and 17.

STATUS OF AMENDMENTS

No proposed amendment after final rejection has been filed in the application.

SUMMARY OF THE INVENTION

The present invention relates generally to the field of DNA sequencing and analysis, and in particular to a computer-implementable method for analysis of DNA markers by processing raw DNA marker profile data into a standardized format that facilitates the analysis of the raw data.

DNA markers are molecular genetic markers identified by studying genomic DNA samples. Each organism has a unique pattern of intron, minisatellite, or microsatellite sequences of nucleotides in their DNA strands, which can be analyzed for mapping and tagging of physical traits of interest, and as indicators of genetic diversity. Genetic mapping offers modern breeders and scientists a powerful array of tools for analyzing the inheritance of important physiological traits in plants and animals. DNA markers also can help determine, regarding diversity questions, how populations of given species are distributed, how genetically distinct different populations are with respect to each other, and how much genetic variation is present in and among populations.

While many different techniques for obtaining DNA markers have been developed in recent years (e.g., RFLP, AFLP, RAPD, DAF, SSR, and VNTR, see specification at pp. 3-5), DNA marker data collection and analysis has not enjoyed the same level of development and has been the main bottleneck in restricting the full exploitation of the potential associated with the various DNA "fingerprinting" methods. Manual interpretation of the raw DNA marker data is tedious, time-consuming and subjective, such that results from different batches even within the same laboratory are difficult to compare. Consequently, it is almost

impossible to exchange and compare quantitative results from different laboratories.

The present invention provides a solution to the shortcomings in the state of the art, by providing a method for standardizing DNA marker profile data such that exchange and comparison of laboratory results can be accomplished among the entire genetics research community.

According to a specific preferred embodiment of the invention, DNA marker fragment peak intensity and size are measured for each fragment in a sample DNA batch that has been processed according to any one of the abovementioned methods, and the results are stored in a memory. The peak intensities are then normalized and classified or transformed into one of five discrete peak levels "ABCD." (see Fig. 2).

The normalized transformed peaks are then aligned into discrete size (i.e., fragment length) bins, each representing a base pair location or position starting from the beginning of a DNA fragment. The DNA marker signature data is then formatted into a standardized data entry record as shown in Fig. 5, wherein in a first field, 501 designates a two-letter organism type, 502 designates a 1-character DNA marker technique, and 503 designates a 1- or 2-primer pair code or probe code. In a second field, 504 indicates the unit size spacing (e.g., 1 base pair), 505 indicates the starting size for the DNA fingerprint, 506

indicates the ending size for the fingerprint, 507 and 508 indicate the marker generation process and species to which the fingerprint pertains, and 509 is the DNA signature sequence obtained through the peak classification and size alignment steps. This is described in the specification at page 13, line 25 to page 15, line 2.

According to another aspect of the invention, Figs. 6(A), 6(B) and 7 disclose a scoring system that enables a quantitative comparison to be performed on the standardized DNA fingerprint signature data records in order to differentiate between similar and unrelated species. This aspect of the invention is described at page 15, line 15 through page 18, line 13 of the specification.

ISSUES

This appeal presents the following issues for decision by the Board:

1) Whether claims 1-7, 9-14, 16 and 17 are unpatentable under 35 U.S.C. § 112, first paragraph, because "the specification, while being enabling for the disclosed method for obtaining DNA fingerprint profile data wherein the step of aligning fragment sizes into discrete bins is by a binning algorithm based on 'spring' and 'rubberband' energies, does not reasonably provide enablement for obtaining DNA fingerprint profile data through alignment by all other means;"

2) Whether claim 17 is unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement as allegedly containing subject matter that was not described in the specification as filed in a manner that reasonably conveyed to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed;

3) Whether claim 17 is unpatentable under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

GROUPING OF CLAIMS

Claims 10 and 11 do not stand or fall together with claims 1-7, 9, 12-14, 16 and 17 for purposes of appeal, but the separate

patentability of each of these claims will be separately argued in this appeal.

ARGUMENT

The § 112 First Paragraph Rejection of Claims 1-7, 9-14, 16 and 17 Is Improper

The rejection of claims 1-7, 9-14, 16 and 17 as being non-enabled is improper and should be reversed. The basis of the rejection is that the specification "does not reasonably provide enablement for obtaining DNA fingerprint profile data through alignment by all other means." The Examiner, however, never explains what "other" means are encompassed by the claims - in other words, the Examiner has failed to construe the claims for purposes of examination.

The Examiner has failed to properly construe the meaning and scope of the claims under the rules of patent application claim interpretation. The Examiner instead has simply compared the claim recitations with the specification, and concluded that the claims are non-enabled because they do not include all the details of the "spring-and-rubberband" binning algorithm as set forth in the specification. This position is contradicted by the Examiner's own acknowledgment that "the specification [is] enabling for the disclosed method for obtaining DNA fingerprint profile data." Final Rejection, pp. 3-4. Of course, if the

specification is enabling for the invention disclosed therein, and the claims as properly construed are supported by that specification, then the claims cannot be unpatentable on the basis of a lack of enablement. Engel Industries, Inc. v. Lockformer Co., 946 F.2d 1528, 20 USPQ2d 1300 (Fed. Cir. 1991) (enablement requirement is met if the description enables any mode of making and using the claimed invention).

Moreover, there is no legal basis for the Examiner's conclusion that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use "the invention commensurate in scope with these claims." The Examiner has failed to articulate the scope of the claims because the Examiner has not construed the meaning of the claims. The claims must be interpreted in light of the specification.

Instead of interpreting the claims in light of the specification, in the present case the Examiner has compared the claims with the specification, and seemingly would require that all the details of the specific exemplary algorithm disclosed in the specification be incorporated into the claims. Contrary to this position, the claims must only particularly point out and distinctly claim the subject matter which the applicant regards as his invention. It is not the function of the claims to recite "all of the details" set forth in the specification. SRI

International v. Matsushita Elec. Corp., 775 F.2d 1107, 227 USPQ 577 (Fed. Cir. 1985) (in banc) (it is not necessary to embrace in the claims or describe in the specifications all possible forms in which the claimed principle may be reduced to practice).

Here, the Examiner does not allege that the specification fails to provide a disclosure that adequately enables one skilled in the art to carry out the claimed invention. Instead, the Examiner alleges that because the claims omit the details set forth in the specification, they are non-enabled. This reasoning runs contrary to the established law on this issue. Under the enablement determination of 35 U.S.C. § 112, the claims must be read in conjunction with the specification to determine if they meet those requirements. S3 Inc. v. nVIDIA, 259 F.3d 1364, 1367 (Fed. Cir. 2001) (if the claims when read in light of the specification reasonably disclose the scope of the invention, then the requirements of § 112 are met). If claims had to include all details of the specification, then there would be no need for claims at all. See SRI v. Matsushita, 775 F.2d 1107 at 1121.

The Examiner's allegation that no guidance, direction of examples are provided such that one of ordinary skill in the art would have known how to practice the claimed invention is wholly unsupported by any evidence of record - the Examiner has failed to properly interpret the claims and also has failed to make any

determination as to the level of ordinary skill in the art or what knowledge such a person would have.

In the Advisory action, the Examiner alleges that the specification mentions a "typical method of binning" that is allegedly described as exhibiting "an unacceptable deviation from the consistency and reproducibility requirements of the present invention." According to the Examiner, the pending claims "broadly encompass[] the 'other means' (although such other means would be unacceptable)." This position is not properly founded. Claims under examination must be given their broadest reasonable interpretation consistent with the specification.

Thus, if the claims are construed as the Examiner as construed them to encompass "other means" allegedly stated in the specification to be unacceptable, then by definition such claim construction is improper because it is inconsistent with the specification and thus unreasonable. A person of ordinary skill in the art would not interpret a claim as covering subject matter described in the specification as being unacceptable.

Accordingly, the rejection of claims 1-7, 9-14, 16 and 17 as being unsupported by an enabling disclosure is improper as a matter of law, and should be reversed.

The Rejection of Claims 10 and 11 Is Improper

Claims 10 and 11 are directed to the scoring system for allowing quantitative comparison of different DNA fingerprint

profiles, as disclosed with respect to Figs. 6(A), 6(B) and 7 of the application. The Examiner has not alleged that the scope of claims 10 and 11 is not enabled for any "other" undisclosed methods for providing a scoring system. Consequently, a *prima facie* case of unpatentability with respect to claims 10 and 11 does not exist on the present record, and it is submitted that claims 10 and 11 are separately patentable on this basis.

The Rejection of Claim 17 Based on Inadequate Written Description Is Improper

The additional rejection of claim 17 as allegedly failing to comply with the written description requirement, is improper and should be reversed.

Appellants vigorously disagree with the Examiner's position that the recitation of computer functional interrelationship with the unique DNA fingerprint data whereby the computer converts the data into a unique DNA fingerprint constitutes new matter. To the contrary, the functionality of the computer that is recited in claim 17 is disclosed and described in Fig. 1 of the application together with the corresponding written description as originally filed. See, e.g., p. 7, ll. 26-30; p. 8, l. 30 - p. 9, l. 2; p. 9, ll. 3-5; p. 14, l. 30 - p. 15, l. 2; claims 12-16 as filed.

The entire purpose of the invention is the development of a standard for facilitating the identification of unique DNA fingerprints. The test for compliance with the written description requirement is whether those skilled in the art would have recognized that applicant was in possession of the claimed invention from the specification and claims as originally filed. Clearly, the entire specification as filed is directed to obtaining DNA fingerprint profile data that is capable of identifying particular DNA. As such, it is not understood how the Examiner can take the position that the concepts set forth in claim 17 as amended cannot be found from the original disclosure. In the Advisory action, the Examiner confuses the use of the DNA fingerprint profile data to identify particular genomic DNA (which is what is set forth in claim 17) with the exemplary "spring-and-rubberband" binning algorithm used to create the data record. In view of the above, the rejection is in error and should be reversed.

The Rejection of Claim 17 Under 35 U.S.C. § 101 Is Improper

Contrary to the position of the final rejection, claim 17 is not directed to stored "non-functional descriptive material" that is simply read or output by a computer. Claim 17 is directed to an article of manufacture that contains specific encoded data representing a DNA fingerprint, that when coupled to a computer

and read by the computer, causes the computer to convert the sequence of classified peak intensity symbols into a unique DNA fingerprint. Thus, claim 17 does in fact recite a functional relationship between the data and the computer in that the data causes the computer to execute a conversion or transformation process that transforms the encoded data from a list of various parameters into a unique DNA fingerprint. It is particularly noted that the MPEP explanation of "nonfunctional descriptive data" recognizes that the functional interrelationship can be created either as part of the stored data, or as part of the computing processes performed by the computer. As such, it is not required that claim 17 recite "executable code that would cause a computer to execute a specific process" as the Examiner would require, in order for claim 17 to constitute a statutory article of manufacture.

Claim 17 defines a useful article of manufacture because it sets forth that the data stored in the computer-readable storage medium is acted upon by a specific process executed by the computer, which causes the data to be converted (i.e., transformed) into a unique DNA fingerprint that identifies a specific trait of a source of genomic DNA. Thus, claim 17 creates the functional interrelationship between the data stored in the medium and the process that is performed by the computer on such data. The MPEP makes clear that the functional

interrelationship does not have to be formed as part of the stored data, i.e. as computer-executable code, but can be part of the computing process performed by the computer on the stored data, which is precisely what is set forth in claim 17.

In the Advisory action, the Examiner simply repeats that the data record is viewed as non-functional descriptive material in the absence of executable code that would cause a computer to execute a specific process. Again, the MPEP defines the required functional interrelationship as being either "part of the stored data or as part of the computing processes performed by the computer." MPEP § 2106 (IV)(B)(1)(b). Since the functional relationship is not required to be in the form of executable code contained in the storage medium itself, it is no ground for rejection that claim 17 does not recite executable code that would cause a computer to execute a specific process.

Consequently, the rejection of claim 17 on non-statutory grounds is not well founded and should be reversed.

CONCLUSION

In view of the foregoing, claims 1-7, 9-14, 16 and 17 are submitted to be directed to a statutory and enabled method, computer product and computer-readable storage medium for obtaining DNA fingerprint profile data, which is completely and sufficiently disclosed and explained in the specification in a

manner that any one of ordinary skill in the art would be able to make and use the invention without undue experimentation. The Honorable Board is respectfully requested to reverse all grounds of rejection and to direct the passage of this application to issue.

Please charge any fee or credit any overpayment pursuant to 37 CFR 1.16 or 1.17 to Deposit Account No. 02-2135.

Respectfully submitted,

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APPENDIX OF CLAIMS ON APPEAL

1. A method for obtaining DNA fingerprint profile data, comprising the steps of:
 - measuring peak intensity and size of each DNA fragment in a sample of genomic DNA;
 - classifying the peak intensities of said fragments according to a predetermined discrete intensity level scale;
 - aligning the sizes of said fragments into corresponding ones of discrete size bins;
 - determining a sequence of fragments according to values of said bins;
 - entering the classified peak intensities of said fragments into a data record in said sequence; and
 - storing the record.
2. The method of claim 1, wherein said sample is obtained by AFLP.
3. The method of claim 1, wherein said sample is obtained by RFLP.
4. The method of claim 1, wherein said sample is obtained by SSR PCR.
5. The method of claim 1, wherein said sample is obtained by VNTR PCR.

6. The method of claim 1, further comprising the step of normalizing the measured peak intensities of said fragments before classifying said peak intensities according to said discrete intensity level scale.

7. The method of claim 6, wherein said discrete intensity level scale comprises at least five discrete peak levels.

9. The method of claim 1, wherein said step of entering comprises the step of creating a data record having:

an information field including

an identification of the source of the genomic DNA,

the method of producing DNA fragments from said source,

the spacing between successive fragments,

the starting size of said fragments, and

the ending size of said fragments; and

a sequence field containing a sequence of said classified peak intensities.

10. The method of claim 9, further comprising the step of scoring a comparison between two data records, including the steps of assigning reward points to matches of peak intensities and penalty points to mismatches of peak intensities, based on the relative magnitude of said peak intensities, comparing said two data records for identical matches at corresponding size positions, comparing said two data records for

identical matches at adjacent size positions, comparing said two data records for non-identical matches at corresponding size positions, and comparing said two data records for non-identical matches at adjacent size positions, and totaling said reward points and penalty points according to found matches and remaining mismatches to obtain a score.

11. The method of claim 10, further comprising the step of obtaining a percentage metric for two compared data records, by obtaining a ratio of said score to a score obtained by matching one of said two data records to itself.

12. A computer program product, comprising:

a computer-readable medium having computer-executable code recorded thereon for obtaining DNA fingerprint profile data, said computer-executable code comprising:

means for measuring peak intensity and size of each DNA fragment in a sample of genomic DNA;

means for classifying the peak intensities of said fragments according to a predetermined discrete intensity level scale;

means for aligning the sizes of said fragments into corresponding ones of discrete size bins;

means for determining a sequence of fragments according to values of said bins;

means for entering the classified peak intensities of said fragments into a data record in said sequence; and

means storing the record in a computer-readable storage medium.—.

13. The computer program product of claim 12, further comprising:

means for normalizing the measured peak intensities of said fragments before classifying said peak intensities according to said discrete intensity level scale.

14. The computer program product of claim 13, wherein said discrete intensity level scale comprises at least five discrete peak levels.

16. The computer program product of claim 12, wherein said means for entering comprises means for creating a data record having:

an information field including

an identification of the source of the genomic DNA,

the method of producing DNA fragments from said source,

the spacing between successive fragments,

the starting size of said fragments, and

the ending size of said fragments; and

a sequence field containing a sequence of said classified peak intensities.

17. A computer-readable storage medium having a DNA fingerprint data record stored therein, said DNA fingerprint data including size and peak intensity of DNA fragments produced from a DNA sample obtained from a source of genomic DNA, said data record comprising:

- an information field including
 - an identification of said source of genomic DNA,
 - the method of producing DNA fragments from said source,
 - the spacing between successive fragments,
 - the starting size of said fragments, and
 - the ending size of said fragments; and
- a sequence field containing a sequence of classified peak intensity symbols, wherein when said storage medium is coupled to a computer and said data record is read from said storage medium by said computer, said computer converts said sequence of classified peak intensity symbols into a unique DNA fingerprint identifying a specific trait of said source of genomic DNA identified in said information field.